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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,290	08/03/2001	David M. Goldenberg	IMMU:015US	5316

37013 7590 12/10/2008
ROSSI, KIMMS & McDOWELL LLP.
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Ashburn, VA 20147

EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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12/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/921,290	Applicant(s) GOLDENBERG, DAVID M.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10,14-18,25-29,32-37,41-44,46 and 48-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10,14-18,25-29,32-37,41-44,46 and 48-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 29, 2008 has been entered.

2. Claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44, 46 and 48-56 are pending.

Claim 1 has been amended.

Claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44, 46 and 48-56 are examined on the merits.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

3. The rejection of claims 1-3, 5, 8-10, 15-18, 25, 26, 32, 33, 37, 41-43, 46, 48, 54, 55 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2001/0018041 A1 (filed April 16, 2001), as evidenced by the Manual of Molecular and Clinical Laboratory Immunology, 7th edition, (Editors: Detrick et al., 2006) is withdrawn in light of Applicant's arguments submitted August 29, 2008.

Claim Rejections - 35 USC § 103

4. The rejection of claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44, 46, 48, 50 and 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2001/0018041 A1 (filed April 16, 2001), as evidenced by the Manual of Molecular and Clinical Laboratory Immunology, 7th edition, (Editors: Detrick et al., 2006), and further in view of Brozek, C. M. et al. (J Clin Lab Immunol. 31(3): 105-9, March 1990), U.S. Patent Application Publication number 2002/0094542 A1 (effective filing date May 3, 1999), Rybak et al. (Proc. Nat. Acad. Sci. USA 89: 3165-3169, April 1992) and Halliwell (J. Am. Vet. Med. Assoc. 181(10): 1088-96, Nov. 15, 1982) is withdrawn in light of Applicant's arguments submitted August 29, 2008.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 5, 8-10, 15-18, 25, 26, 32, 33, 37, 41-43, 46, 48, 54, 55 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2001/0018041 A1 (filed April 16, 2001). The publication discloses methods of

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treating humans, as well as dogs, cats, horses, cows, pigs, goats, sheep and ungulates (i.e. llamas and alpacas) having CD40+ malignancies, B-cell lymphomas and leukemias with compositions consisting of single treatment dosages of ⁹⁰Y-labeled anti-CD20 antibodies (including human, chimeric, humanized and bispecific antibodies) with chemotherapeutic agents, immunosuppressive and radiotherapy, see page 3, sections 0027-0033; section 0082 bridging pages 7 and 8; page 8, section 0091; page 9, sections 0092 and 0097; page 10, sections 0105 and 0106; page 11, sections 0107, 0109-0112; and page 12, sections 0113-0115. Yttrium-90 (⁹⁰Y) is art known to be cytotoxic dose of beta radiation. The therapeutic composition also comprises a combination of two or more naked antibodies against different epitopes and a fusion protein of antibody combinations, see page 3, section 0027; and page 10, sections 0105 and 0106.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44, 46, 48, 50 and 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2001/0018041 A1 (filed April 16, 2001), and further in view of Brozek, C. M. et al. (J Clin Lab Immunol. 31(3): 105-9, March 1990), U.S. Patent Application Publication

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number 2002/0094542 A1 (effective filing date May 3, 1999), Rybak et al. (Proc. Nat. Acad. Sci. USA 89: 3165-3169, April 1992) and Halliwell (J. Am. Vet. Med. Assoc. 181(10): 1088-96, Nov. 15, 1982). The teachings of publication '8041 have been presented in the 102(e) rejection. This publication does not teach the method wherein the therapeutic composition further comprises an anti-CD74, cytokine, drug or toxin and the antibody component comprises a hapten with an attached therapeutic agent, as well as the treated B-cell disorders are autoimmune diseases selected from the group consisting of immune-mediated autoimmune hemolytic anemia, rheumatoid arthritis, systemic lupus erythematosus, bullous pemphigoid, pemphigus, and thrombocytopenia.

However, U.S. Patent Application Publication number 2002/0094542 A1 teaches the claimed method, wherein a therapeutic composition comprising conjugates composed of antibodies, cytotoxins and cytokines capable of binding more than one antigen for the treatment of cancer, as well as autoimmune diseases, see page 3, sections 0032 and 0046; page 9, section 0131; and page 14, section 0191. The therapeutic agents can be conjugated with haptenic groups, see page 12, section 0165; page 16, section 0213; and page 18, section 0243. Brozek teaches that anti-MHC class II antibodies have been used to treat autoimmune diseases and that autoantibodies that bind HLA-DR inhibit rheumatoid factor production in peripheral blood mononuclear cells from rheumatoid arthritis patients. Rybak teaches the use of chimeric antibodies linked to toxins such as RNase to target tumor cells, see page 3165, abstract and introduction. Halliwell teaches autoimmune diseases of domestic animals, see entire document. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the

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claimed invention was made to utilize the different combinations of the therapeutic compositions for treatment of B-cell lymphomas and leukemias, including autoimmune diseases in domestic animals. It would have been *prima facie* obvious to add to the composition an additional antibody such as an anti-HLA-DR and a RNase toxin because Brozek teaches that anti-MHC class II antibodies are useful in the treatment of autoimmune diseases and publication '041 teaches a combination of antibodies for effective treatment and the cytotoxic potential of the RNase toxin is increased and functional experiments have proven tumor growth inhibitory activity. One of ordinary skill in the art would have been motivated to manufacture such a medicament in order to effectively treat companion animals/domestic animals because all publications set forth treatment of B cell malignancies targeting the cancer antigens, see all documents in their entireties.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached Monday through Saturday on 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
06 December 2008
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643